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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,470	01/21/2000	MORTEN SOEGAARD	P01938US0	6355

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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/11/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.



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This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 2/15/02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 35-84 is/are pending in the application.  
Of the above, claim(s) 47-84 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 35-46 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) 35-84 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on 112-0100 is/are objected to by the Examiner. APPROVED BY THE DRAFTSMAN

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Claims 35-84 are pending.

Applicant's election without traverse of Group I (claims 35-50) in Paper No. 13, filed 1/15/01) is acknowledged.

Claims 47-50 are withdrawn as directed to nonelected species.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The declaration fails to claim priority to U.S. provisional application 60/053,211 or Swedish application 9704170-1.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The disclosure is objected to because of the following informalities: Numerous of the references cited at pages 60-65 fail to provide the ending page number of the reference.

Appropriate correction is required.

Claims 35-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 35 it is unclear as to what the targetting moiety is directed to in its targetting --to the target cell?

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In claim 43, it is not clear what is intended by “immunogenicity in human sera”, because “immunogenicity” is art understood as a term referring to the capability of a substance to induce an immune response in an immunocompetent host organism, or at the least, in a culture of immunocompetent cells. Since no sera contain immunocompetent cells, no substance can be “immunogenic” when combined with human sera. It is suggested this claim be amended to recite --seroreactivity in human sera or decreased immunogenicity in humans-- (e.g. as disclosed at page 15).

Claims 35-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 35 contains new matter because the “targetting moiety” is not limited to one that targets the target cell, as recited in the specification and original claim 1.

By not thus limiting the nature of the targetting moiety, applicant has unduly broadened the scope of what is targetted (e.g. targetting of accessory cells would be within the scope of the invention).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35, 37-41 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belfrage et al. (Immunology, 90, 183, 1997).

Belfrage et al. teach (page 188) coadministration of a wild type super antigen conjugated to a targetting antibody and of IL-2 to increase the immunotherapeutic killing of cancer cells.

Claims 35, 37-38, 41 and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Lando et al. (J. Immunol., 157, 2857, 1996).

Lando et al. (Fig. 4) teach coadministration of a superantigen conjugated to targetting antibody and of IL-2 in a culture system in which the target cells express a tumor antigen.

Claims 35 and 37-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over  
*in view of*  
Belfrage et al., Abrahmsen et al. (WO 96/01650) and Antonsson et al. (WO 97/36932).

Belfrage et al. teach as supra. Abrahmsen et al. and Antonsson et al. teach that it is advantageous to use, instead of wild type superantigens, superantigens that have

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been mutated to have a decreased ability to bind MHC class II (instant claim 42), or superantigens that have been mutated to have less seroreactivity/immunogenicity (instant claim 43), and chimeric superantigens (instant claim 44) in order to provided for lowered toxicity and lowered immunogenicity of superantigens administrated to a patient. Thus, in the combination treatments taught by Belfrage et al., it would have been obvious to employ targetted superantigens that have been modified in the manner taught by Abrahmsen et al. and Antonsson et al. Though WO 97/36932 post-dates provisional application 60/053,211 applicant's disclosure admits that this (or any corresponding U.S. application) is prior art.

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

In response to this requirement, please provide a copy of each of the following items of art referred to in the specification: the Belfrage thesis (1996) and Belfrage et al. (1997b).

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the

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scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan , can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

June 17, 2002

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182 1644